

REMARKS

This is a response to the final Office Action mailed on August 15, 2011. No fee is due in connection with this response. The Director is authorized to charge the petition for extension of time and any additional fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00694 on the account statement.

Claims 11 and 21-23 are rejected in this application. Claims 1-10, 12-13, 15 and 19-20 were previously withdrawn. Claims 14 and 17-18 were previously canceled without disclaimer. In the Office Action, Claims 11 and 21-23 are rejected under 35 U.S.C. §112; and Claims 11 and 21-23 are rejected under 35 U.S.C. §103. In response, Claim 11 has been amended. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 11 and 21-23 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. In response, Claim 11 has been amended to address the informalities cited by the Patent Office. Based on at least these noted reasons, Applicants believe that Claims 11 and 21-23 fully comply with 35 U.S.C. §112, second paragraph. Accordingly, Applicants respectfully request that the rejection of Claims 11 and 21-23 under 35 U.S.C. §112 be withdrawn.

In the Office Action, Claims 11 and 21-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over to U.S. Patent Publication No. 2002/0127211 to Brassart et al. ("*Brassart*") in view of the printed publication to Birch et al. ("*Birch*"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

Independent Claim 11 recites, in part, a method for inducing a pattern of gut barrier maturation in an infant similar to that observed with breast-feeding. The method comprises administering to the infant a nutritional composition comprising a lipid selected from the group consisting of arachidonic acid, docosahexanoic acid and combinations thereof, a non-digestible oligosaccharides comprising a milk-derived oligosaccharide, and at least one of a *Bifidobacterium* CNCM I-2170, *Bifidobacterium* CNCM I-2168, *Bifidobacterium* CNCM I-2169, *Lactobacillus johnsonii* CNCM I-1225, *Lactobacillus paracasei* CNCM I-2116,

Bifidobacterium lactis ATCC 27536, or *Bifidobacterium longum* BB536. An example of a milk-derived oligosaccharide is sialyllactose.

During postnatal development, a newborn intestine experiences a process of maturation that ends by the establishment of a functional barrier to macromolecules and pathogenic bacteria (*i.e.*, gut closure). Different studies with infants and animal models show that the maturation of the barrier is faster in breast-fed than in formula-fed newborns, and could aid in explaining the higher prevalence of allergy and infection in infants fed formula than in those fed with mother milk. See specification, page 1, lines 13-19.

An impressive number of different mechanisms integrate this barrier such as mechanisms that act synergistically to protect the host from the luminal aggressions. The first barrier includes the intestinal epithelium, which is a continuous monolayer of columnar epithelial cells sealed together by protein complexes such as the tight junctions. The second is a non-specific barrier composed by mechanisms that protect the mucosal surface as saliva, gastric acidity, mucus layer, proteolytic digestion, alkaline intestinal pH, unstirred layer and intestinal peristalsis. The gut immune system is able to respond selectively and specifically to the foreign molecules and pathogen microorganisms. Finally, and not less important, intestinal flora directly and indirectly protect against host invasion by pathogens and macromolecules with antigenic properties. See specification, page 2, line 21-page 3, line 4.

In accordance with the present claims, Applicants have surprisingly found that gut barrier function or gastrointestinal health in infants may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. See specification, page 3, lines 2-5. The microorganisms of the present claims, which differ in their ability to survive in the different parts of the gastro-intestinal tract, can be incorporated into a cocktail. The bioactive ingredients such arachidonic acid/docosahexanoic acid and a non-digestible oligosaccharides comprising a milk-derived oligosaccharide can be added to the microorganism cocktail in order to reinforce their effects by stimulating the maturation of barrier mechanisms different to those stimulated by the microorganisms. See specification, page 3, lines 11-17. The microorganisms of the present claims are designed to release the beneficial substance(s) at a certain desired location of the gut and may be administered to a recipient, whereupon they will lyse at the respective location in the

gut depending on the sort of pretreatment undergone by the microorganism. See specification, page 7, lines 11-28.

Brassart and *Birch* alone or in combination fail to disclose or suggest each and every element of independent Claim 11. *Brassart* and *Birch* alone or in combination fail to disclose or suggest a nutritional composition comprising a non-digestible oligosaccharides comprising a milk-derived oligosaccharide as required by independent Claim 11. *Brassart* and *Birch* alone or in combination also fail to disclose or suggest a lipid selected from the group consisting of arachidonic acid, docosahexanoic acid and combinations thereof, a non-digestible oligosaccharides comprising a milk-derived oligosaccharide, and at least one of the recited microorganism in a single nutritional composition as required by independent Claim 11. Finally, *Brassart* and *Birch* alone or in combination fail to disclose or suggest administering the nutrition composition thereby inducing a pattern of gut barrier maturation in an infant similar to that observed with breast-feeding as required by independent Claim 11.

Brassart discloses a method for increasing or facilitating the absorption of minerals from the diet. A nutritional composition that contains *lactobacilli* is enterally administered to a mammal. The nutritional composition is suitable for the treatment or prophylaxis of subjects having mineral deficiencies, to compensate for physiological deficiencies due to a diet low in minerals, or to satisfy major physiological requirements for minerals in patients. Nevertheless, *Brassart* fails to disclose the use of a milk-derived oligosaccharide anywhere in his disclosure. *Brassart* further fails to teach or even suggest inducing a pattern of gut barrier maturation in an infant.

Birch discloses the effect of long-chain polyunsaturated fatty acid supplementation of formula in term infants after weaning at six weeks of age. The results showed that the critical period during which the dietary supply of long-chain polyunsaturated fatty acids can influence the maturation of cortical function extends beyond 6 weeks of age. Accordingly, the focus of *Birch's* formulations and study are on visual acuity and stereoacuity. *Birch* fails to teach inducing a pattern of gut barrier maturation in an infant using a nutritional composition and the skilled artisan would have no reason to arrive at same in the absence of hindsight. Moreover, *Birch* fails to disclose the use of a milk-derived oligosaccharide anywhere in his disclosure.

For at least the reasons discussed above, the cited references fail to disclose or suggest each and every element of independent Claim 11. Moreover, the cited references fail to even recognize the advantages, unexpected benefits and/or properties of a method for inducing a pattern of gut barrier maturation in an infant similar to that observed with breast-feeding in accordance with the present claims. As a result, Applicants respectfully submit that independent Claim 11, along with any claims that depend from Claim 11, is novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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